

<b>Examiner-Initiated Interview Summary</b>	Application No.	Applicant(s)	
	10/681,103	FEI ET AL.	

**All Participants:**

(1) JOHN PAK

*Non-  
6/12/07*

(3) \_\_\_\_\_

(2) FAYE ZHENGXING

(4) \_\_\_\_\_

**Date of Interview:** 31 May 2007

**Time:** \_\_\_\_\_

**Type of Interview:**

Telephonic  
 Video Conference  
 Personal (Copy given to:  Applicant  Applicant's representative)

**Exhibit Shown or Demonstrated:**  Yes  No

If Yes, provide a brief description: *Examiner Pak faxed written instructions for amending the claims and the specification in order to assist the pro se applicant in correcting the deficiencies in this case and to expedite prosecution. A copy of the transmitted fax is attached hereto.*

**Part I.**

Rejection(s) discussed:

Claims discussed:

*See below and attached fax.*

Prior art documents discussed:

**Part II.**

**SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:**

*See Continuation Sheet*

**Part III.**

It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.  
 It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

  
 (Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed:

Examiner Pak initially called Faye Zhengxing to ask whether the inventors would be open to telephone and fax communications in order to make corrections and expedite prosecution. Ms. Zhengxing indicated that inventors would appreciate such handling of this case. Examiner Pak therefore worked on all the corrections and changes that would be needed to allow this case. Numerous deficiencies and required changes were noted in a faxed communication (attached hereto for the record). Ms. Zhengxing stated that she and Mr. Fei would review the changes and get back to the Examiner.



## Patent Technology Centers

### Facsimile Transmission

To: Name: Faye Zhengxing and inventors of 10/681103  
Company:  
Fax Number:  
Voice Phone: 912125672713

From: Name: Examiner John Pak  
Official Fax Number: (571) 273-8300  
Official After Final Fax Number: (571) 273-8300  
Voice Phone: 571-272-0620

37 C.F.R. 1.6 sets forth the types of correspondence that can be communicated to the Patent and Trademark Office via facsimile transmissions. Applicants are advised to use the certificate of facsimile transmission procedures when submitting a reply to a non-final or final Office action by facsimile (37 CFR 1.8(a)).

#### Fax Notes:

You asked me to fax to 212-567-2713, so here it is.

Please review and let me know if you can reply in writing (as discussed on the next page) at your earliest convenience.

John Pak  
Primary Examiner  
Art Unit 1616  
Tel: 571-272-0620  
Fax: 571-273-0620

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Date and time of transmission: Thursday, May 31, 2007 6:06:32 PM  
Number of pages including this cover sheet: 09

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Part of Interview Summary

Please review the changes set forth herein. If you agree to these changes, you must state (via reply fax, preferably) in writing, if accurate:

- (1) all inventors agree to authorize the changes to the claims and changes to the specification, as set forth in this communication; and
- (2) provide signatures of authorization of as many inventors as possible.

Note, claims 5-6 are identical to the version I sent you earlier (3/29/2007).

Reciting proprietary names such as ACA-104 2A or ACA-104 2B does not add anything more to what you already have. You are free to call the composition whatever you want in commercial settings, but these names do not belong in the claims. The claim is defined by what it contains. I removed the \* marks next to many ingredients because it is confusing to have them there.

Note, the fifth inventor did not sign the declaration. This makes the declaration defective. I can allow the case, but you must timely file a supplemental declaration that has the fifth inventor's signature.

Note, we only have on file the first page of the certified copy of the Chinese priority application. You must timely file a fully copy to be granted the foreign priority.

I reserve an opportunity to make further changes (only with your additional authorization), if such further changes are deemed necessary upon carrying out final preparations for allowance.

If you have any questions, I can try to answer them. Also, I refer you again to page 2 of the Office action of 6/21/2005, which provides information about securing the services of a registered patent attorney or agent.

Part of Interview Summary

Amendment to the Claims

Cancel claims 7, 8 and 9.

Rewrite claims 5 and 6 as set forth below.

Claim 5. (Currently amended) A health pill for reducing the harmful effects of cigarette smoking comprising:

0.2 to 14.6 mg of sodium selenite;

3.5 to 67 ml of 1.85%  $\beta$ -cyclodextrin;

0.2 to 10 g of Vitamin E;

3 to 35 mg of Vitamin A;

0.3 to 27 mg of butylated hydroxytoluene;

7 to 200 mg of riboflavin;

7 to 200 mg of nicotinic acid; and

33 to 2000 mg of pyridoxine hydrochloride.

Claim 6. (Currently amended) The health pill of claim 5, further comprising 0.07 to 6 g of ascorbic acid.

Amendment to the Specification

Amend pages 7, 13-15, 19 and 21 as shown on the following pages.

Delete all four pages of Appendix 2.

Part of Interview Summary

Not only do our liquid additive and health pill reduce or inactivate the toxicity in the seven major hazardous chemicals in tobacco smoke, they also transform some of the hazardous chemicals into healthful vitamins. Similarly, our liquid additive and health pill work effectively on carcinogenic compounds such as nitrosamine and ammonia in tobacco smoke. Ammonia, after counteracted, will lose its chemical irritation. Even after some ammonia enters the human body and raises the level of ammonia in blood, the VB6 in our health pill will combine the ammonia with  $\gamma$ -aminobutyric acid transformed from decarboxylated glutamic acid and the resultant urea will be discharged out of the human body (7); nitrosamine can be inactivated by the anti-oxidants in the health pill before or after nitrosamine forms in the human body. For the preparation for liquid additive, see Table 1.

Eleven years ago, we started the experiments on toxicity reduction. The Test Report by Shanghai Institute for Toxicity Control of Chemical Products proves that we reduced tar by 61.02% and nicotine by 81.18%. With oxidants compound, catalysts, and full oxidization when necessary, we currently reduced nicotine by 90-97 percent and turned it into nicotinic acid (VB3); we reduced tar by 75 to 85 percent. Compared with some well-known "light" cigarettes, our cigarettes had 50 percent less nicotine and 25 percent less tar in tobacco smoke.

## 2. Health Pill to Enhance Smokers' Health and Prevent Diseases:

The components in tobacco smoke are very complicated and complex. They can invade all kinds of human systems and organs and cause various diseases. The most threatening and common are cancers, cardiovascular diseases and respiratory diseases. How to prevent these diseases effectively is our unprecedented challenge. The invention of our health pill was inspired by the theory of free radical, which states that free radicals are responsible for aging and degeneration of the human as well as other species (9). According to this theory, free radicals are the biochemical basis for many hazardous diseases such as cancers, cardiovascular disease, atherosclerosis, central nervous system, arthritis, muscle atrophy, and congenital malformation. With oxygen, free radicals' initiator will oxidize many biochemical elements inside and outside human cells. For instance, when the unsaturated fatty acid

Selenium and other anti-oxidants also have excellent effect on respiratory diseases. An expert at Connell University and a Chinese scholar point out that a diet rich in anti-oxidants will strengthen lung functions and prevent respiratory diseases such as asthma, pulmonary emphysema and chronic bronchitis. The effect of these anti-oxidants on the lung has a lot to do with smoking. The experts also state that taking in B-carotin with selenium and high dosage anti-oxidants is a very good way to prevent cells from damages by hazardous biochemical elements (28). A medical study took 18,162 adults as their samples to examine the relationship between the ingredients (we adopted in our health pill) of their diet and their blood and their lung functions in a period of six years. The experts found strong evidence to prove, through comparing the variables such as gender, age, bodily fat, race, income, and smoking or non-smoking behavior, that these ingredients are closely related to these adults' lung functions. Their findings also indicate that those natural ingredients in food are not as effective on smokers' lung functions as that of their chemical counterparts (such as vitmin C and E) on both smokers and non-smokers (28).

d) Selenium and Other Smoking Related Diseases:

In addition, this health pill also prevents other smoking related diseases such as premature aging, weak immunity, tobacco amblyopia, mouth leukoderma and other diseases caused by harmful radioactive material in tobacco smoke.

e) Our Creative Invention:

Over the past 30 years selenium and its compound GSH-PX have displayed wonderful performances in animal and clinic experiments in various countries, but the activity of GSH-PX decreases because of oxidization other factors. Even with the supplement of selenium, GSH-PX will not resume its activity due to a series of chemical reactions such as oxidization, replacement, resolve, and counteraction. GSH especially loses its function as an anti-oxidant after it is changed into an oxidant GSSG.

We tackled the essential problem: how to reduce GSSG back to GSH. We believe we could not just mix more GSH with glutamic acid, ~~systeine~~ and glycine. Instead,

↗  
Spelling error,  
Correct to "Cysteine"

we must find a synthetase and reduce the oxidized GSSG in the human body. GSSG is an oxidized enzyme protein, a complicated complex. Though we knew there is GSSG-R (GSSG's reductase) in the human body, it is not active enough. We knew we were in need of a strong co-enzyme as catalyst to reduce GSSG back to GSH.

After a long search and study, we finally found a co-enzyme to reduce GSSG back to GSH. We were greatly encouraged by this finding. With this co-enzyme, we could resume the activity of GSH in every way. Moreover, in case GSSG-R is insufficient, the two components in riboflavin in the health pill – flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD) – will resume the activity of GSSG-R to the normal level. We believe this is a breakthrough in generating an unfailing effect to prevent smokers from getting various smoking related diseases. For the preparation for the health pills, see Table 2.

### 3. The Causes of Addiction and Our Invention in Smoking Cessation:

It is a consensus of medical experts that when nicotine enters the human brain, brain cells will release a great deal of dopamine and glutamic acid, the major causes of addiction to cigarettes (or addiction to other drugs) (22, 23, 24). An expert from Virginia Institute of Technology reports that they have separated a compound from tobacco, which will inhibit monoamine oxidase (MAO), a major enzyme in the brain to resolve dopamine (27); another series of research papers from a state lab in New York City indicate that the MAO concentration in a smoker's brain is 40 percent lower than that of a non-smoker. This is the reason why a smoker has higher dopamine content in the brain than a non-smoker (27). Some researchers from Columbia University state in "Science" magazine that when nicotine enters the brain, it greatly increases the release of glutamic acid in the brain. They detailed the reasons why it is an accomplice in causing nicotine addiction (24).

The United States and Canada are doing clinic experiments on  $\gamma$ - VINYL GABA, GVG, a medicine produced by Aventis in Europe for children's epilepsy, to see if it could be used to detoxicate tobacco smoke and facilitate smoking cessation. GVG may reduce the dopamine in the smoker's brain and thus help him/her break the

*to dopamine*

addiction to nicotine. We believe, however, that it will not be enough to only reduce dopamine in the brain, because glutamic acid, through decreasing MAO's activity, makes it harder to resolve and inactivate dopamine. Glutamic acid might be one of the causes that stabilizes the addiction to nicotine and other drugs. Furthermore, glutamic acid will also damage brain cells and cause the death of brain cells. In addition, iron, if over taken or stored in the human body, will also release glutamic acid in the brain. Excessive iron may be stored in the body for many reasons: Some people tend to supplement too much iron to cure anemia. Some people cook in pots or pans made of iron, drink too much beer or grape wine, or who have iron residue caused by excessive blood transfusions, or indigestion by intestine. Furthermore, there are other factors causing the release of glutamic acid. For instance, lack of vitamin B6 and nicotinic acid will increase the pathologic absorption of iron; lack of vitamin E and other anti-oxidants will cause iron chronic poisoning. Not only will these factors cause more glutamic acid in the brain, they will also cause other diseases. To eliminate the addiction to nicotine, therefore, we must appropriately reduce dopamine, glutamic acid, and at the same time reduce the excessive iron in the human body. We adopted the following three methods:

(a) Strengthening MAO's activity with Copper Compound and Enhancing Copper's function with Manganese Compound:

Since glutamic acid lowers the copper content in the brain and copper is an important component of MAO, glutamic acid, therefore, may decrease the activity of MAO. [Kong Xiangrui reports that glutamic acid injection will lower the copper content in human blood serum (6. p. 173)].

To supplement copper and manganese compound, however, is not easy, because they are metal oxidants, which may counteract with the majority of the anti-oxidants in the health pill. Furthermore, several hours after copper compound enters the human body, it will compound into ceruloplasmin in the liver. This ceruloplasmin, however, cannot go through the blood-brain barrier to increase copper. Later we came up with the idea of adding copper and manganese into the cut tobacco. When the smoker lights up, he/she will absorb the metals through

# Table 1

## APPENDIX

### PRESCRIPTION, PREPARATION & USE OF THE LIQUID ADDITIVE TO TOBACCO (ACA-104-1)

Order of Sprinkle	Components & Concentration of Ingredients	Quantity (3) Content Range % (Per 100g Tobacco)	Preparation
	Tween-80	0.7-15ml	Dissolve them for use later; label the solution as A.
	Hot water (55-60°C)	50-100 ml	
(1)	Cerium dioxide	7-134mg	Dilute sulfuric acid to 20% solution, take out 6.665ml solution ( $H_2SO_4$ 1.333ml), into which put 44.45mg of $CeO_2$ , stir them for use later; label this solution as B;
	Sulfuric acid (5%-20%) V/V	0.2-10 ml	
	Selenium dioxide	0.4-8mg	Dissolve 2mg selenium dioxide into 1ml water;
	B-cyclodextrin	0.1- 4 g	Put 1.85g B-Cyd into 100ml water at 50-60°C; Take out 12.973 ml (which equals B-Cyd 0.24g) to mix the $SeO_2$ sol. above; stir till all dissolved; label it as Solution C; Put the A, B, C three solutions above together, stir them thoroughly; sprinkle them onto 100 g tobacco; blend them thoroughly and put it aside for 30 minutes;
(2)	Hydrogen peroxide (3% or 6%)	30-600 ml	Sprinkle 3% Hydrogen peroxide 167 ml onto 100 g tobacco above, blend them thoroughly and stir it for 30 minutes;
	*Potassium permanganate	15-150 mg	Dissolve $KMnO_4$ to 1% solution; take out 4.445 ml (which equals 44.45 mg $KMnO_4$ ); Dilute Sulfuric acid to 5% solution; take out 6.66 ml (which equals 0.333 ml $H_2SO_4$ ); label this solution as D;
(3)	*Cupric Sulfate	45-400 mg	Dilute $CuSO_4$ to 5% solution; take out 2.666ml (which equals 133.33 mg $CuSO_4$ ); label this solution as E; Mix D with E; and stir them thoroughly for use later;
	Cupric Oxide B-cyclo-dextrin	20-270 mg 0.1-4 g	Grind fine $CuO$ (66.67mg) and activated $MnO_2$ (33.335mg); Dissolve 1.333 g B-Cyd into 72.054 ml hot water, into which put the above $CuO$ and

**Table 2**

APPENDIX 5

**PRESCRIPTION, PREPARATION & USE  
OF THE HEALTH PILL ENCLOSED IN CIGARETTE PACK  
(ACA-104-2A, B)**

Kind	Name of Components	Quantity	Preparation	Signature (Sig.)
		Content (per 100g tobacco) Range %		
	*Sodium selenite	0.2- 14.6 mg	Dissolve Na <sub>2</sub> SeO <sub>3</sub> (3.65 mg) in 1 ml water;	
	B-cyclodextrin (1.85%)	0.5-30 ml	Add 2 ml B-Cyd (1.85%) to the above solution; stir them thoroughly;	<u>Dose of orange pill:</u> For those who smoke 20 cigs daily, take 2 pills before eating in the morning or half an hour before smoking; Take 2 pills one hour after lunch;
(A)	*Vitamin E	0.2-10 g		
	*Vitamin A	3-35 mg	Grind them fine	
	Butylated hydroxytoluene	0.3-27 mg		
	Riboflavin	7-200 mg		
	Nicotinic acid	7-2000 mg	Mix them;	
	Pyridoxine hydrochloride	33-2000 mg		
			Mix all the above thoroughly and make four orange coated pills.	For those who smoke 10 cigs daily, take 1 pill twice a day at the same time as stated above.
(B)	*Ascorbic acid	0.07-6 g	Make two white-coated pills with 400 mg ascorbic acid..	<u>Dose of the white pill:</u> For those who smoke 20 cigs daily, take 2 pills one hour after the last cig before the bedtime.  For those who smoke 10 cigs, take 1 pill at the time stated above.

Part of Interview Summary